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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,758	06/10/2005	Hiromu Habashita	Q88484	6854
65565	7590	09/16/2009		
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2100 PENNSYLVANIA AVE. NW				
WASHINGTON, DC 20037-3213				
EXAMINER				
JARRELL, NOBLE E				
ART UNIT		PAPER NUMBER		
1624				
MAIL DATE		DELIVERY MODE		
09/16/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/538,758

**Applicant(s)**

HABASHITA ET AL.

**Examiner**

NOBLE JARRELL

**Art Unit**

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 6, 8-10, 23, 28-30 and 33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1, 6 and 10 is/are allowed.
- 6) ☒ Claim(s) 8, 23, 28 and 33 is/are rejected.
- 7) ☒ Claim(s) 9, 29 and 30 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/29/2009 has been entered.
2. In the current claim set, claims 1, 6, 8, 9, 10, 23, 28, 29, 30, and 33 are pending. These claims are being examined on the merits.

### ***Response to Amendment***

3. The rejections under 35 U.S.C. 102 and 103 have been overcome by the amendment filed 6/29/09.
4. The rejections under 35 U.S.C. 112 2<sup>nd</sup> paragraph have been overcome by the amendment filed 6/29/2009.
5. Claim 33 has been searched only with respect to the elected group because a unique structural query is required for each of the eight compound groups described in the 11/26/2007 restriction. It is noted that applicants elected group I in the response filed 12/28/2007. Group I encompassed a compound in which ring A was azepane and ring B was pyrimidine,

### ***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:  

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
7. Claims 8, 23, 28 and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 8 (and 23 because it depends on claim 8), ring C is unclear. Ring C is only defined by

two characteristics: it must contain at least one nitrogen atom and it is a fully saturated 4-15-membered heterocyclic group. This definition is unclear because the ring can be a monocyclic ring such as aziridine or a bicyclic ring system such as decahydro-1*H*-benzo[*c*]azepine. In addition, ring C may contain 1 or 2 nitrogen atoms, 1 or 2 oxygen atoms, and/or 1 sulfur atom. Depending on the presence of other heteroatoms in the ring, ring C could control classification of a compound embraced by formula (I-B). For example, if the ring is azepane, its classification could be class 540, subclass 612. If the ring contains an oxygen or sulfur, the classification is class 540, subclass 544. In claim 28, applicants specify that a second therapeutic agent is present to be used in combination with a compound of claim 1 or 8. Possible examples of these agents are included in dependent claims 29 and 30 as well as in the specification (page 69, lines 19-30). However, these agents are included in the broad combination claim. Claim 33 is unclear due to several factors. What specific rings are intended for rings D and E? The descriptions provided in the claim cover any ring system (monocyclic or polycyclic) with zero or more heteroatoms. Ring J is not defined within this claim. The claim states "ring J represents;". It is possible to determine that ring J is a nitrogen-containing ring, but the other ring atoms are not defined.

#### **Conclusion**

8. Claims 1, 6, and 10 appear free of the prior art of record.
9. Claims 29 and 30 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NOBLE JARRELL whose telephone number is (571)272-9077. The examiner can normally be reached on M-F 7:30 A.M - 6:00 P.M. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Noble Jarrell/  
Patent Examiner, Art Unit 1624

**/James O. Wilson/  
Supervisory Patent Examiner, Art Unit 1624**